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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/511,345	10/15/2004	Kazuaki Hirasawa	38331-0005	3763
4372 7590 05/24/2007 ARENT FOX PLLC 1050 CONNECTICUT AVENUE, N.W. SUITE 400 WASHINGTON, DC 20036			EXAMINER MARX, IRENE	
			ART UNIT 1651	PAPER NUMBER
			MAIL DATE 05/24/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

**Office Action Summary**

Application No.

10/511,345

Applicant(s)

HIRASAWA ET AL.

Examiner

Irene Marx

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 03 May 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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### DETAILED ACTION

The amendment filed 5/3/07 is acknowledged. Claims 1-6 are being considered on the merits.

#### *Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2-3 and 5-6 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The rejection is stated in the last Office action.

#### **Response to Arguments**

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

On the one hand applicant argues that the Examples demonstrate that the mutated microorganisms can be easily derived (Response, page 4). Yet on the other hand applicant argues that the Tsubokura *et al.* method of mutating does not produce the required productivity, even though substantially the same method of mutagenesis is used.

It cannot be readily assessed how one of ordinary skill in the art can obtain the mutants required to make the process of claims 2-3 and 5-6 without undue experimentation. It is noted that the mutagenesis protocol followed relies on chemical mutagenesis with nitrosoguanidine, the effects of which are random and unpredictable. Therefore, in the absence of a specific screening method, it is deemed that the **specific** strains actually produced are not readily available to the public and should be deposited for this purpose.

Therefore the rejection is deemed proper and it is adhered to.

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The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1 and 4 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Tsubokura *et al.*

The claims are directed to a process of mutating and culturing a strain such as a mutant of strain E-396 for the production of canthaxanthin..

Tsubokura *et al.* teach to a process of mutating and culturing a strain such as E- 396, wherein the mutant strain Y-1071 is cultured for the production of canthaxanthin as claimed. See, e.g., Example 3.

### **Response to Arguments**

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

Regarding the higher yields of canthaxanthin, a comparison between each of the ratios obtained in Table 4 and each of the ratios obtained in Table 7 shows “a higher mass percentage of canthaxanthin relative to that produced by the parent strain”.

Therefore, applicant’s argument is without merit and the rejection is maintained.

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Claims 1-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tsubokura *et al.*

The claims are directed to a process of mutating and culturing a strain such as a mutant of strain E-396 for the production of canthaxanthin in certain amounts.

Tsubokura *et al.* teach to a process of mutating and culturing a strain such as E- 396, wherein the mutant strain Y-1071 is cultured for the production of canthaxanthin as claimed. See, e.g., Example 3.

The reference differs from the invention as claimed in that the amounts of canthaxanthin and other pigments products are not the same as claimed. However, the reference teaches methods of mutation suitable to obtain further mutants and in addition discloses that the manipulation of process conditions, such as concentration of dissolved oxygen affects the results obtained.

One of ordinary skill in the art would have had a reasonable expectation of success in using the process of Tsubokura *et al.* of mutation and selection and of manipulating oxygen content in the medium to obtain greater yields of canthaxanthin with the mutant obtained, for example.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to modify the process of Tsubokura *et al.* by subjecting the strains known to product canthaxanthin to further mutation and selection, if necessary, and/or manipulating process conditions to maximize the production of the valuable carotenoid canthaxanthin.

### **Response to Arguments**

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

Applicant argument that the present invention uses a mutant strain that produces a higher mass percentage of canthaxanthin relative to that produced by the parent strain has not been substantiated for any and all microorganisms having the required homology. It is noted that applicant has not demonstrated that the asserted productivity is the effect of the mutation rather than of process conditions that achieve the higher results of canthaxanthin for any and all mutants obtainable. No particular mutation/selection protocols are claim designated to achieve

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the functional results required.. The process of "inducing a mutation" as disclosed by Tsubokura and the instant invention have not been particularly distinguished for any parent strain and for any mutant of any microorganism having the required sequence homology.

The scope of the showing must be commensurate with the scope of claims to consider evidence probative of unexpected results, for example. In re Dill, 202 USPQ 805 (CCPA, 1979), In re Lindner 173 USPQ 356 (CCPA 1972), In re Hyson, 172 USPQ 399 (CCPA 1972), In re Boesch, 205 USPQ 215, (CCPA 1980), In re Grasselli, 218 USPQ 769 (Fed. Cir. 1983), In re Clemens, 206 USPQ 289 (CCPA 1980). It should be clear that the probative value of the data is not commensurate in scope with the degree of protection sought by the claim.

No claim is allowed.

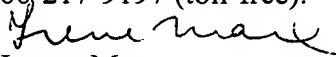
**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (571) 272-0919. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300 .

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Irene Marx  
Primary Examiner  
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